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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/592,011	10/22/2007	Stuart Edward Bradley	NC-10007/US	7007
38724 7590 09/21/2010 OSI PHARMACEUTICALS, INC. 420 Saw Mill River Road Ardsley, NY 10502				
EXAMINER				
POWERS, FIONA				
ART UNIT		PAPER NUMBER		
1626				
MAIL DATE		DELIVERY MODE		
09/21/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/592,011

**Applicant(s)**

BRADLEY ET AL.

**Examiner**

Fiona T. Powers

**Art Unit**

1626

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 15 and 19-27 is/are pending in the application.
- 4a) Of the above claim(s) 24-27 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21-23 is/are allowed.
- 6) ☒ Claim(s) 1, 15, 19 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

Claims 1, 15 and 19 to 27 are pending in the application.

Receipt is acknowledged of the amendment filed July 9, 2010, which has been entered in the file.

***Election/Restrictions***

Claims 24 to 27 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 16, 2009.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 15, 19 and 20 are rejected under 35 U.S.C. 102(a) as being anticipated by Nakamura et al. (CA 2465382), of record.

The reference discloses the claimed pharmaceutical compositions comprising a compound of instant formula I and a pharmaceutically acceptable carrier where the compound corresponds to instant formula I where Z is a bond; and R<sup>3</sup> is C<sub>1-4</sub>alkylaryl. Note, for example, Compound Nos. 5-15 and 5-17 on pages 196 and 197; page 33, lines 22 to 31; and Sections 12 to 20 on page 48, line 29 to page 50, line 1.

### ***Response to Arguments***

Applicant's arguments filed July 9, 2010 have been fully considered but they are not persuasive. With respect to the rejection of claims 1, 15, 19 and 20 under 35 U.S.C. 102(a) over Nakamura et al. (CA 2465382) Applicants state that the definition of R<sup>3</sup> in claim 1 appears to exclude Nakamura since in claim 1 when R<sup>3</sup> is C<sub>1-4</sub>alkylaryl then any of the rings can be optionally substituted with 1-3 substituents. However, Examples 5-15 to 5-19 of Nakamura all require the alkyl portion of C<sub>1-4</sub>alkylaryl to be substituted which is not claimed herein. Applicants further state that for Example 5-15 of Nakamura the alkyl portion of C<sub>1-4</sub>alkylaryl would need to be substituted with methyl.

In the rejection of claims 1, 15, 19 and 20 over Nakamura set forth herein only Examples 5-15 and 5-17 of Nakamura are

relied upon. In both of these Examples the alkyl portion of C<sub>1-4</sub>alkylaryl is not substituted with methyl (or dimethyl), rather the alkyl portion of C<sub>1-4</sub>alkylaryl is a branched C<sub>2</sub>- or C<sub>3</sub>-alkylene. Note that the instant specification on page 6 defines that for any substituent that begins with "alk" the alkyl portion can be in a linear or branched configuration.

***Allowable Subject Matter***

Claims 21 to 23 are allowed.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fiona T. Powers whose telephone number is 571-272-0702. The examiner can normally be reached on Mon - Thurs 6:15 am - 2:45 pm (in the office) and Fri 7:00 am - 5:30 pm (telework day).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Fiona T. Powers/  
Primary Examiner, Art Unit  
1626

ftp  
September 17, 2010